UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

22-20471-CR-WILLIAMS/MCALILEY

CASE NO. _____

18 U.S.C. § 371
18 U.S.C. § 981(a)(1)(C)

UNITED STATES OF AMERICA

v.

ANGELA MARIA GIRON,

Defendant.

_____/

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times relevant to this Information:

1. Clinical investigations, also known as clinical trials, were research studies conducted on voluntary human subjects designed to answer specific questions about the safety or effectiveness of new drugs. Drug developers, or "sponsors," initiated and took responsibility for clinical trials.

2. The United States Food and Drug Administration ("FDA") was responsible for ensuring that drugs intended for human use were safe and effective. The FDA relied on the truthfulness and accuracy of the results of clinical trials to make regulatory decisions about the approval of new drugs.

3. Before beginning a clinical trial, sponsors were required to provide the FDA with extensive information regarding the proposed trial, including a detailed investigational plan known as a "study protocol." The study protocol described, among other things, the eligibility and

exclusion criteria for study subject selection, schedules of tests and procedures, drug and dosage regimens, a description of observations and measurements to be made to fulfill the clinical trial's objectives, the length of the study, and the health outcomes to be measured by the study. Clinical trials were required to be conducted according to the study protocol, as well as any applicable laws and FDA regulations.

4. Sponsors generally retained contract research organizations ("CROs") to oversee and manage various aspects of clinical trials. Sponsors and CROs typically contracted with multiple trial sites to perform clinical trials. Under such an arrangement, each individual clinical trial site was responsible for identifying and screening study subjects, ensuring the subjects met eligibility criteria, enrolling them into the clinical trial, performing the clinical trial, gathering data, and reporting the data to the sponsor and/or CRO, in accordance with the study protocol.

5. Sponsors generally contracted with third-party companies to manage the study data system, process the study data submitted by the clinical trial sites, and to track, send to and receive from the clinical trial sites the study medications. Sponsors also generally contracted with third-party laboratories to receive, test, and analyze samples obtained from subjects that were sent by the clinical trial sites to the laboratories.

6. An Institutional Review Board was an organization formally designated to monitor and review a clinical trial throughout its course. An Institutional Review Board had the authority to review, require modifications to, or disapprove research.

7. Each clinical trial site had a clinical investigator, also known as a principal investigator. The clinical investigator was the individual responsible for conducting the clinical investigation at that clinical trial site and ensuring that the clinical trial was conducted according to the study protocol and in compliance with all applicable FDA regulations. Responsibilities of the clinical investigator included personally conducting or supervising the clinical trial, including

all requirements regarding the qualification of the subjects; obtaining informed consent from subjects; dispensing study medication; collecting and reporting data; reporting adverse events; and ensuring that all employees working on the study met those same obligations.

8. The clinical investigator also was required, by regulation, to prepare and maintain records relating to clinical trials. These records, known as "case histories," included adequate records of the disposition of the study drug, including dates and quantities of drugs dispensed to subjects; informed consent forms and medical records for each subject participating in the clinical trial; and records of all observations and other data pertinent to the investigation for each subject administered an experimental drug. The clinical investigator had the authority to delegate certain responsibilities to clinical trial site staff working on the clinical trial.

9. The FDA had the authority to inspect a clinical investigator to ensure that the clinical investigator was complying with all applicable laws and regulations in conducting clinical trials. The FDA's inspection authority included the authority to review case histories and other records maintained by the clinical investigator.

10. A clinical investigator provided to the sponsor and/or the CRO information about each subject screened for and enrolled in the study, including his or her medical history, laboratory results, and reaction to the drug under study. The sponsor then provided the information to the FDA for its use in evaluating whether the drug was safe and effective and should be approved for its intended use.

The Defendant and the Co-Conspirators

11. AMB Research Center, Inc. ("AMB Research Center") was a medical clinic located in Miami, Florida that conducted clinical trials of new drugs for pharmaceutical companies and other sponsors.

12. Defendant **ANGELA MARIA GIRON** was a resident of Miami, Florida and was the clinical investigator for the CDAD clinical trial.

13. Co-Conspirator 1 was a resident of Miami, Florida. Co-Conspirator 1 was the co-owner of AMB Research Center and served as its Vice-President/Director, President/Director, lead study coordinator, clinical research coordinator, and study coordinator.

14. Co-Conspirator 2 was a resident of Miami, Florida. Co-Conspirator 2 was the co-owner of AMB Research Center and served as its Vice-President/Director, clinical research coordinator, and study coordinator.

15. Co-Conspirator 3 was a resident of Miami, Florida. Co-Conspirator 3 served as recruiting and data entry specialist, site manager, and pharmacist at AMB Research Center.

The Clinical Trial

16. Co-Conspirator 1, Co-Conspirator 2, and Co-Conspirator 3 conducted various clinical trials on behalf of sponsors and CROs located throughout the United States at AMB Research Center.

17. In or around March 2016, AMB Research Center was contracted to conduct a clinical trial designed to evaluate the safety and efficacy of an investigational drug intended to treat persons with Clostridium difficile-associated diarrhea.

18. Prior to beginning the CDAD clinical trial, Co-Conspirator 1, on behalf of AMB Research Center, entered into a "Clinical Trial Agreement" with the CRO and sponsor. The Clinical Trial Agreement required, among other things, that AMB Research Center conduct the CDAD clinical trial in strict accordance with the Clinical Trial Agreement and study protocol. The Clinical Trial Agreement also required AMB Research Center and any persons or entities

performing services on its behalf to act in accordance and compliance with all applicable FDA regulations.

19. The Clinical Trial Agreement required AMB Research Center to obtain informed consent from subjects to participate in the CDAD clinical trial, and to notify the CRO, sponsor, and Institutional Review Board in writing of any deviations from the study protocol and to review all case report forms and case histories for accuracy and completeness.

20. The study protocol required subjects to meet certain eligibility criteria to be enrolled in the CDAD clinical trial. For example, among other things, the study protocol required subjects to have a diagnosis of mild-moderate or severe CDAD; first occurrence or first recurrence of CDAD within three months of enrollment and diarrhea within 24 hours prior to enrollment; a positive Clostridium difficile test and stool test from the same stool sample collected no more than 72 hours prior to enrollment; and signed written informed consent forms before any study-mandated procedure could be conducted.

21. The study protocol contained exclusion criteria that prohibited investigational staff site members or their relatives from participating in the CDAD clinical trial.

22. The study protocol required each subject to be assigned a unique subject identification number. The clinical investigator/delegate was required to keep a subject identification code list showing the subject's name, date of birth, address, or any other locally accepted identifiers.

23. The study protocol required subjects participating in the CDAD clinical trial to complete a stool diary, a CDAD DaySyms Pro Questionnaire, a questionnaire entitled "Work Product and Activity Impairment: CDAD," and a study drug journal. The subjects were required to provide the two completed questionnaires, stool diary, and study drug journal to AMB Research Center, from which AMB Research Center was required to enter the data in the appropriate study database.

24. The Clinical Trial Agreement between AMB Research Center, the CRO, and sponsor included a budget and schedule of payments the sponsor would pay AMB Research Center per enrolled subject, provided that AMB Research Center's services were properly performed in accordance with the study protocol and the Clinical Trial Agreement. The schedule of payments in the Clinical Trial Agreement included each informed consent, examination, procedure, test, CDAD questionnaire, office visit, interview, or other event required under the study protocol, in addition to other fees and conditional procedures. The Clinical Trial Agreement also included payments the sponsor would pay AMB Research Center for screen failed subjects found ineligible to participate in the CDAD clinical trial, including applicable visit fees performed in accordance with the study protocol. The Clinical Trial Agreement required that AMB Research Center not be paid for subjects who were enrolled without a properly executed consent form and who did not meet eligibility and exclusion criteria.

25. The Clinical Trial Agreement and study protocol required AMB Research Center, in turn, to pay individual subjects for travel costs not to exceed $120.00 per enrolled subject in accordance with the study protocol scheduled visit. Reimbursement for subject travel costs exceeding $120.00 required prior written approval from the CRO or sponsor.

26. The Clinical Trial Agreement provided for subject stipend/compensation to be paid to AMB Research Center on a quarterly basis based on completed visits. Pursuant to the Clinical

Trial Agreement, AMB Research Center was required to promptly refund to the CRO any patient stipend/compensation paid by the CRO to AMB Research Center that was not actually paid to the subject.

27. The Clinical Trial Agreement required AMB Research Center to be responsible for compensating all other entities and individuals involved in conducting the study.

COUNT 1
Conspiracy
(18 U.S.C. § 371)

1. The General Allegations section of this Information is re-alleged and incorporated as though fully set forth herein.

2. Beginning in or around September 2015, and continuing at least through in or around March 2018, in Miami-Dade County, in the Southern District of Florida and elsewhere, the defendant,

ANGELA MARIA GIRON,

did willfully, that is, with the intent to further the object of the conspiracy, and knowingly combine, conspire, confederate, and agree with Co-Conspirator 1, Co-Conspirator 2, Co- Conspirator 3, and others known and unknown to the United States Attorney, to commit an offense against the United States, that is: to knowingly, and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that the pretenses, representations, and promises were false and fraudulent when made, and, for the purpose of executing the scheme and artifice, did transmit and cause to be transmitted, by means of wire communication in interstate and foreign commerce, certain writings, signs, signals, pictures, and sounds, in violation of Title 18, United States Code, Section 1343.

PURPOSE OF THE CONSPIRACY

3. It was the purpose of the conspiracy for **ANGELA MARIA GIRON** and her co-conspirators to unlawfully enrich themselves by, among other things: (a) securing contracts to conduct the CDAD clinical trial; (b) fabricating and falsifying documents, study data, and other items related to the CDAD clinical trial to obtain payments and inflate the payments due and owing to **ANGELA MARIA GIRON** and her co-conspirators under the Clinical Trial Agreement; (c) receiving payment for the CDAD clinical trial by making material false and fraudulent representations; and (d) using the fraudulently obtained funds for the defendant's personal use and benefit, the use and benefit of others, and to further the conspiracy.

MANNER AND MEANS OF THE CONSPIRACY

The manner and means by which **ANGELA MARIA GIRON** and her co-conspirators sought to accomplish the object and purpose of the conspiracy, among others, the following:

4. **ANGELA MARIA GIRON** and her co-conspirators created false and fraudulent study subjects using the personal identification information of non-study participants and otherwise ineligible individuals, and submitted the information associated with the purported study subjects to the CDAD clinical trial database systems in order to induce the CRO, acting on behalf of the sponsor, to make payments to AMB Research Center to which it was not entitled.

5. In order to prevent the sponsor, the CRO, and the FDA from learning that **ANGELA MARIA GIRON** and her co-conspirators created false and fraudulent data for the CDAD clinical trial and submitted false and fraudulent data to the CDAD clinical trial database systems, **ANGELA MARIA GIRON** and her co-conspirators created false and fraudulent case histories, laboratory tests, and subject study documents of the purported study subjects to make it appear that the subjects had, among other things, satisfied the eligibility criteria to participate in

the CDAD clinical trial, signed informed consent forms in the presence of **ANGELA MARIA GIRON** to participate in the CDAD clinical trial, signed informed consent forms in the presence of the clinical investigator to participate in the CDAD clinical trial, received a physical examination, provided laboratory samples, received and had taken the study medication, completed the handwritten questionnaires, study drug journals, and stool diaries, and received payment for visits to AMB Research Center as part of the CDAD clinical trial.

6. **ANGELA MARIA GIRON** and her co-conspirators falsely and fraudulently represented that **ANGELA MARIA GIRON** obtained informed consent from all purported subjects, as required by the study protocol, to be included in the CDAD clinical trial.

7. As part of their effort to conceal the fact that AMB Research Center falsified study data, Co-Conspirator 1 sent and received emails on behalf of AMB Research Center regarding the CDAD clinical trial.

8. As a result of the false and fraudulent misrepresentations made by **ANGELA MARIA GIRON** and her co-conspirators, the CRO, acting on behalf of the sponsor, paid AMB Research Center to conduct the CDAD clinical trial. Thereafter, **ANGELA MARIA GIRON** and her co-conspirators used the funds for their personal use and benefit, the use and benefit of others, and to further the conspiracy.

9. To induce the sponsor and/or the CRO to enter into a Clinical Trial Agreement with and provide money to **ANGELA MARIA GIRON** and her co-conspirators, **ANGELA MARIA GIRON** and her co-conspirators made and caused others to make numerous materially false and fraudulent statements to the sponsor, the CRO, and/or the FDA.

OVERT ACTS

In furtherance of the conspiracy, and to accomplish the object and purpose thereof, at least one of the following acts, among others, were committed in the Southern District of Florida, and

elsewhere, by at least one co-conspirator:

1. **ANGELA MARIA GIRON** and Co-Conspirator 1 signed a letter dated May 7, 2017, addressed to the Institutional Review Board, which contained false and fraudulent misrepresentations, including that **ANGELA MARIA GIRON** was present for all subjects' informed consent and gave each subject the time to understand, read, and resolve any questions prior to signing the informed consent form.

2. On May 8, 2017, Co-Conspirator 1 emailed that letter to the Institutional Review Board and copied **ANGELA MARIA GIRON.**

3. On October 2, 2017, Co-Conspirator 1 sent an electronic mail communication to an employee of the CRO requesting AMB Research Center's final CDAD clinical trial site payment which was based on and included payments for subjects who did not participate in the CDAD clinical trial in compliance with the study protocol.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE
(18 U.S.C. § 981(a)(1)(C))

1. The allegations of this Information are hereby re-alleged and by this reference fully incorporated herein for the purpose of alleging criminal forfeiture to the United States of America of certain property in which the defendant, **ANGELA MARIA GIRON,** has an interest.

2. Upon conviction of a violation of Title 18, United States Code, Section 371, as alleged in this Information, the defendant shall forfeit to the United States of America, any property, real or personal, which constitutes, or is derived from proceeds traceable to such offense pursuant to Title 18, United States Code, Section 981(a)(1)(C).

3. The property subject to forfeiture as a result of the alleged offense includes, but is not limited to, a sum of money equal in value to the total amount of proceeds the defendant derived

from the offense and funds involved in or derived from the alleged offense, and may be sought as a forfeiture money judgment.

4. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third person;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be subdivided without difficulty,

the United States shall be entitled to the forfeiture of substitute property under the provisions of Title 21, United States Code, Section 853(p).

All pursuant to Title 18, United States Code, Section 981(a)(1)(C), and the procedures set forth at Title 21, United States Code, Section 853, as incorporated by Title 28, United States Code.

JUAN ANTONIO GONZALEZ
UNITED STATES ATTORNEY

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CONSUMER PROTECTION BRANCH

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CONSUMER PROTECTION BRANCH

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA

v.

ANGELA MARIA GIRON,

_____/

Defendant.

CASE NO.: _____

CERTIFICATE OF TRIAL ATTORNEY*

Superseding Case Information:

New Defendant(s) (Yes or No) _____
Number of New Defendants ____
Total number of New Counts ____

Court Division (select one)

☑ Miami ☐ Key West ☐ FTP
☐ FTL ☐ WPB

I do hereby certify that:

1. I have carefully considered the allegations of the indictment, the number of defendants, the number of probable witnesses and the legal complexities of the Indictment/Information attached hereto.

2. I am aware that the information supplied on this statement will be relied upon by the Judges of this Court in setting their calendars and scheduling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C. §3161.

3. Interpreter: (Yes or No) **Yes**
   List language and/or dialect: Spanish

4. This case will take **0** days for the parties to try.

5. Please check appropriate category and type of offense listed below:

(Check only one)		(Check only one)
I	☑ 0 to 5 days	☐ Petty
II	☐ 6 to 10 days	☐ Minor
III	☐ 11 to 20 days	☐ Misdemeanor
IV	☐ 21 to 60 days	☑ Felony
V	☐ 61 days and over	

6. Has this case been previously filed in this District Court? (Yes or No) **No**
   If yes, Judge _____ Case No. _____
7. Has a complaint been filed in this matter? (Yes or No) **No**
   If yes, Magistrate Case No. _____
8. Does this case relate to a previously filed matter in this District Court? (Yes or No) **Yes**
   If yes, Judge **Moore** Case No. **22-20431-CR (SEALED)**
9. Defendant(s) in federal custody as of _____
10. Defendant(s) in state custody as of _____
11. Rule 20 from the _____ District of _____
12. Is this a potential death penalty case? (Yes or No) **No**
13. Does this case originate from a matter pending in the Northern Region of the U.S. Attorney's Office prior to August 8, 2014 (Mag. Judge Shaniek Maynard? (Yes or No) **No**
14. Does this case originate from a matter pending in the Central Region of the U.S. Attorney's Office prior to October 3, 2019 (Mag. Judge Jared Strauss? (Yes or No) **No**

By: _____

KARLA-DEE CLARK
DOJ Trial Attorney
Court ID No. A5502714

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: ANGELA MARIA GIRON

Case No:

Count #: 1

Title 18, United States Code, Section 371

Conspiracy

*** Max. Term of Imprisonment: 5 years**
*** Mandatory Min. Term of Imprisonment (if applicable): N/A**
*** Max. Supervised Release: 3 years**
*** Max. Fine: $250,000 or twice the gross gain or loss from the offense**

***Refers only to possible term of incarceration, supervised release and fines. It does not include restitution, special assessments, parole terms, or forfeitures that may be applicable.**

AO 455 (Rev. 01/09) Waiver of an Indictment

UNITED STATES DISTRICT COURT

for the

Southern District of Florida

United States of America)
v.) Case No. 22-20471-CR-WILLIAMS/MCALILEY
)
Angela Maria Giron,)
Defendant)

WAIVER OF AN INDICTMENT

I understand that I have been accused of one or more offenses punishable by imprisonment for more than one year. I was advised in open court of my rights and the nature of the proposed charges against me.

After receiving this advice, I waive my right to prosecution by indictment and consent to prosecution by information.

Date: _____

_____
Defendant's signature

_____
Signature of defendant's attorney

_____
Printed name of defendant's attorney

_____
Judge's signature

_____
Judge's printed name and title